MAY 2 2 2002

K021491

GE Medical Systems

P.O. Box 414

Milwaukee,WI 53201

March 15, 2002

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21CFR 807.87 (h)

Submitter: Larry A. Kroger

Senior Regulatory Programs Manager

who may be contacted at (414) 544-3894 or by FAX (414) 544-3863

Summary prepared March 15, 2002

Device Name :Hispeed CT/e Dual Computed Tomography system.

Classification Name : Computed Tomography X-ray system

Manufacturer: GE Hangwei Medical Systems Co. Ltd.
No.2, North Yong Chang Street
Beijing Economic Technological Development Zone
Beijing 100176, P.R.China

Distributor: General Electric Medical Systems
3000 North Grandview Blvd
Waukesha,WI 53188

Marketed Device:

The Hispeed CT/e Dual Computed Tomography system is of comparable type and substantially equivalent to currently marketed computed Tomography systems that comply with the same or equivalent standards and have the same intended uses.

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Device Description:

The Hispeed CT/e Dual Computed Tomography system consist of a gantry, patient support, operator console ,computer and associated accessories.

Materials: All construction and materials are complaint with 21 CFR Subchapter J and IEC 60601-1 and are equivalent to CT/e (K993645)

Design: The system is designed to be a head and whole body CT scanner utilizing a solid state detector and an intutive Operator Console with similar features to the CT/e (K993645)

Indications for Use:

The Hispeed CT/e Dual Computed Tomography System is indicated for head and whole body X-ray Computed Tomography applications.

Comparison with Predicate Device:

It is the opinion of GE Hangwei Medical systems that the Hispeed CT/e Dual Computed Tomography system is comparable type and substantially equivalent to currently marketed head and whole body X-ray Tomography systems with respect to design,material composition,energy source and radiation characteristics . It will comply requirements of the IEC60601-1 series of standards.

Adverse Effects on Health:

Potential electrical, mechanical ,fire and radiation hazards are identified in the attached Risk Analysis and controlled by:

· System verification and validation to insure performance to specifications, regulatory requirements and user requirements.

· Adherence to Industry and International Standards(UL/IEC/CSA)

Conclusions:

Use of the Hispeed CT/e Dual Computed Tomography system do not result in any new potential safety risks and performs as well as, or better than devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

GE Medical Systems, Inc.
% Mr. Wolfram Gmelin
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTOWN CT 06470

Re: K021491
Trade/Device Name: HiSpeed CT/e Dual Computed Tomography System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: May 8, 2002
Received: May 9, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K021491

Device Name: Hispeed CT/e Dual Computed Tomography System

Indications For Use:

The Hispeed CT/e Dual Computed Tomography System is indicated for head and whole body X-ray Computed Tomography applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021491